**Pharmaceutical and Food Safety Bureau,
Ministry of Health, Labour and Welfare**

**Translated by Office of Safety Ⅰ,
Pharmaceuticals and Medical Devices Agency**

PFSB/ELD Notification No. 0304-1
PFSB/SD Notification No. 0304-1
March 4, 2013

To: Directors of Prefectural Health Departments (Bureaus)

From: Director of Evaluation and Licensing Division,
Pharmaceutical and Food Safety Bureau,
Ministry of Health, Labour and Welfare

Director of Safety Division,
Pharmaceutical and Food Safety Bureau,
Ministry of Health, Labour and Welfare

Publication of Risk Management Plan

The Ministry of Health, Labour and Welfare (MHLW) previously issued notifications entitled "Risk Management Plan Guidance" PFSB/SD Notification No. 0411-1 and PFSB/ELD Notification No. 0411-2 dated April 11, 2012 issued jointly by the Director of Evaluation and Licensing Division and the Director of Safety Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare, and "Risk Management Plan templates and instructions to authors" PFSB/ELD Notification No. 0426-2 and PFSB/SD Notification No. 0426-1 dated April 26, 2012 issued jointly by the Director of Evaluation and Licensing Division and the Director of Safety Division, Pharmaceutical and Food Safety Bureau, Ministry of Health, Labour and Welfare (herein after referred to as "the Risk Management Plan templates and instructions to authors") and described handling of guidance, form and submission for development of a Risk Management Plan.

Because of the importance of publication of Risk Management Plans to ensure smooth implementation of post-marketing surveys and studies as well as promoting proper use of drugs with gaining the greater understanding of healthcare professionals about drug safety measures, the MHLW determined to make the Risk Management Plans public as described below. Please inform Marketing Authorization Holders (MAHs) under your jurisdiction of this notification.

1. Scope
   a) Risk Management Plans of new drugs and biosimilars/follow-on biologics for which approval applications are submitted on or after April 1, 2013, submitted to the Pharmaceuticals and Medical Devices Agency (PMDA) based on the section 3-(1) -(i) and -(ii) of the Risk Management Plan templates and instructions to authors.
   b) Risk Management Plans submitted to PMDA by a Marketing Authorization Holder (MAH) because new safety concerns have been identified since April 1, 2013.
   c) Risk Management Plans submitted to the PMDA by the MAH due to above a) or b) with changing the plans.

2. The scope of Risk Management Plan that will be published
   Of a Risk Management Plan submitted to the PMDA, the part of the plan that will be published is from the section 1 "Outline of Risk Management Plan" to the section 5.3 "The list of Risk minimization Plan" with a cover including a summary of an item and a history of change (with the exception of seal impression by submitter, a name and contact information of person in charge).

3. Preparation for Risk Management Plan that will be published
   a) The MAHs and applicants for marketing authorization should create a document with a title "Risk Management Plan for ●● (brand name) " and put the cover on the published document clearly stating that the submitter shall be held any responsible for the content and the right of any information described in the document. In the case of more than one brand name , the document should be identified each brand name such as that the title on the cover should be "Risk Management Plan for ●● (brand name) / ▲▲ (brand name) ."
   b) If a Risk Management Plan is submitted to the PMDA by joint names of the relevant parties for their products, the document should be made in joint

names as well.

c) The document should be submitted as a pdf file with no copy protection. And the pdf file should be put a file name in accordance with the Annex of this notification.

4. Submission of Risk Management Plan that will be published

a) After a Risk Management Plan is submitted based on the section 3 of the Risk Management Plan templates and instructions to authors, the PMDA notifies the submitter to file the document electronically for publication. After the notification from the PMDA, the submitter should file the document created for publication to the International Safety Information Section, Office of Safety Ⅰ, PMDA under the following b) within 5 business days.

b) The submitter should file the document through:

- e-mail by attaching it.

  Note:

  - File size should not be larger than 3MB. If the file size is larger than 3MB, the submitter should file the document through electronic media and not send the document as a separate attachment.
  - The submitter should put the name of submitter, the non-proprietary name/brand name of the drug, and the date of market authorization in the body of e-mail.
  - The submitter should file to Risk Management Plan publication coordinator, Office of Safety Ⅰ, PMDA (rmp@pmda.go.jp).

- electronic media

  Note:

  - The submitter should use CD-R or DVD-R and put the word of "RMP", the name of submitter, the non-proprietary name/brand name of the drug, and the date of market authorization on the electronic media.
  - The submitter should file to Risk Management Plan publication coordinator, Office of Safety Ⅰ, PMDA that the MAHs and applicants for marketing authorization are submitting it to.

c) The filed document will be promptly posted on the Medical Product Information Web Page in PMDA's website.

5. A part of the appended form in the Management Plan templates and instructions to authors is revised as stated below.

a) The following statement is added to the section 8 "Organizational structure for Risk Management Plan" in the page of the Guide for developing Risk Management Plan of the "Risk Management Plan templates and instructions to authors".

- The section 6.2 "Organizational structure for Safety management activities" should be clearly expressed the name of preparer.

b) In the section 9 "Reference materials" in the page of the Guide for developing Risk Management Plan of the "Risk Management Plan templates and instructions to authors", the description of "Report on the Review Results" is revised to "Report on the Deliberation Results"